

20 September 2018
EMA/274125/2018
Inspections and Human Medicines Pharmacovigilance Division

Agenda – Twelfth Pharmacovigilance Stakeholder forum

24 September 2018, 10:00-16:00, Room 3/E, European Medicines Agency (EMA) - 30 Churchill Place, Canary Wharf, London, E14 5EU, UK

Time	Agenda item	Speakers
<i>09:30 – 10:00 Registration and reimbursement arrangements</i>		
10:00 – 10:10	Welcome and Introduction (Fergus Sweeney, EMA)	
10:10 – 10:35	Pharmacovigilance in 2018: achievements and challenges (Peter Arlett, EMA)	
Session 1 – Patient involvement in pharmacovigilance processes		
Session 1 - Co-Chairs: Juan Garcia (EMA), Marco Greco (EPF)		
10.35-10.50	Overview of current patient involvement	Maria Mavris (EMA)
10.50-11.05	Public hearings. Lessons from valproate and quinolones	Nathalie Bere (EMA)
11.05-11.20	Conceptual framework for patients engagement	Patrick Brown (University of Amsterdam)
11.20-11.30	Open discussion	
<i>11.30- 11.45 Coffee break</i>		
Session 2 - Listening to the public. Case study - Valproate		
Session 2 - Co-Chairs: Sabine Straus (PRAC chair), Albert van der Zeijden (IAPO)		
11.45-12.00	Account of events and outcomes	Efstratia Vatzaki (EMA)
12.00-12.15	Patient's perspective	Francois Houyez (EURORDIS)

Time	Agenda item	Speakers
12.15-12.30	Pharmacist's perspective	Raymond Anderson (PGEU)
12.30-12.45	Doctor's perspective (neurologist)	Reetta Kalviainen (EAN)
12.45-13.00	Industry perspective	Eric Teo (EFPIA)
13.00-13.15	Impact of Valproate views	Priya Bahri (EMA)
13.15-13.30	Open discussion	All
13.30 – 14.30 <i>Lunch break</i>		
Session 3 - Looking forward. Pharmacovigilance in the next 5 years		
Session 3 - Co-Chairs: Sabine Straus (PRAC chair), Peter Arlett (EMA)		
14.30-14.45	Patients' vision	Marco Greco (EPF)
14.45-15.00	Pharmacist's vision	Jan De Belie (PGEU)
15.00-15.15	Doctor's vision	Catarina Matias (UEMO)
15.15-15.30	Industry vision	Vicki Edwards (EU Industry Associations' representative)
15.30-15.45	Open discussion	All
15:45 – 16:00	Conclusions	Peter Arlett
16:00 <i>Close of meeting</i>		